Soft tissue Reconstruction of Gustilo-Anderson Grade IIIB Open Extra-Articular Tibial Fractures at a Tertiary Hospital in Cape Town, South Africa: A Retrospective Case Series

by

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Declaration

I, ***Elyas Barouni***, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Elyas Barouni

Contents

Chapter 1

Literature Review

Epidemiology of tibial fractures

Epidemiological studies report open long bone fractures to occur at an estimated rate of 11.5 per 100,000 population per year; where, tibial diaphysis fractures were found to occur in 44.7% of all patients, and 56% of them were classified as grade 3 Gustilo-Anderson. These extreme injuries are frequently found in multiple injured patients due to the correlation with high-energy collisions, such as motor and pedestrian-vehicle accidents (MVA and PVA).[2] Noteworthy here, however, is that these findings are not comparable to developing countries as their data is limited.

Classifications of tibial fractures

Classification systems and injury severity ratings are designed to direct decision-making in management, aid with prognosis, forecast complications, predict outcomes, assist documentation, and promote communication.[3] The most commonly used scoring systems for open tibial fractures include the Gustilo-Anderson classification, Ganga Hospital scoring system, and the Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification.

Gustilo-Anderson first published their classification for open long bone fractures in 1976.[4] They classified injuries into three groups after an intraoperative assessment, which is as follow:

- Type 1: an open fracture with a wound of less than one centimetre long and clean.
- Type 2: an open fracture with a laceration more than one centimetre long without extensive soft tissue damage, flaps or avulsions.
- Type 3: either an open segmental fracture, an open fracture with extensive soft tissue damage, or traumatic amputation.

Type 3 injuries were further stratified after high rates of complications were identified with this group injuries. The following classification was developed:[5]

- Type 3a: adequate soft-tissue coverage of bone with extensive soft-tissue laceration or flaps.

- Type 3b: extensive soft-tissue loss with periosteal stripping, bone exposure and the need for soft tissue cover.
- Type 3c: arterial injury requiring repair.

This classification system continues to be widely used in clinical practice and research as it is highly practical, and helps with prognosis, and therapy. Since the initial description though, many changes have occurred worldwide, resulting in a loss of consistency and poor reliability of the interobserver.[6, 10]

Management of open tibial fractures

While regularly investigated, the management of open tibial fractures is still controversial. The treatment of open tibia fractures involves several aspects, with certain principles cardinal to successful outcomes. These principles include:

1. Early systemic antibiotics and anti-tetanus toxoid;
2. Effective surgical debridement;
3. Fracture Stabilization; and
4. Reconstruction of soft tissue.[7]

Use of Antibiotics

Systemic Antibiotics

The effectiveness of systemic antibiotics in reducing the rates of infection in open fractures was first demonstrated in 1974 by Patzakis *et al*. In a prospective study of 310 open fractures, it was found that the rate of infection decreased from 13.9% in patients without antibiotics to 9.8% and 2.4% in patients receiving it respectively in patients that received either penicillin/streptomycin or cephalothin.[8] Patzakis' work was further expanded by Gustilo and Anderson in 1976, which led to the recommendation that 1st generation cephalosporin was the antibiotic of choice.[4] Due to their possible nephrotoxicity, the authors initially cautioned against the use of aminoglycosides. In a follow-up study by Gustilo *et al*. in 1984, it was found that 77% of all infections in type 3 injuries were due to gram-negative organisms (Enterobacter or Pseudomonas). This led to a change in their antibiotic protocol for type 3 injuries, adding an aminoglycosides or to use a third generation cephalosporin.[9] In 1989, Patzakis and Wilkins found that the infection rates decreased from 7.4% to 4.7% when intravenous antibiotics were administered within 3 hours of injury.[10]

This study was conducted on all open fractures, but the antibiotic and wound care regimen was not standardized.

The suggested recommendations for antibiotics have remained unchanged, despite extensive work since then. In 2017, following a review of the literature, Carver *et al.* released their recommendations for systemic antibiotic prophylaxis.[11] The choice of antibiotic should be guided by the Gustilo-Anderson classification which cites the following:

- Type 1 and 2 injuries should receive a first-generation cephalosporin only.
- In patients with B-lactam allergy, clindamycin is the best alternative.
- Type 3 injuries an aminoglycoside (gentamycin) should be added.
- A third-generation cephalosporin (ceftriaxone) or piperacillin/tazobactam is a good alternative to the above combination, although further research still required.
- In case of faecal or potential clostridial contamination, consider adding penicillin or
  anaerobic cover.

There is also no clear consensus on the duration of prophylactic antibiotics, with most recommendations suggesting antibiotic therapy for one to three days.[12] Also, Patzakis *et al.* [10] and Dellinger *et al.*[13] could not specify the period of antibiotic therapy and its subsequent infection rates. Nevertheless, some authors suggest that the discretion of the treating physician is to extend the time until the wound closure. [14,15]

The recommendations for AO and British Orthopaedic Association (BOA) or the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) for trauma (BOAST4) are the most current applied guidelines that are focused on management. The official antibiotic prophylaxis recommendations for AO in open fractures are as follows:[3]

- Type 1 and 2: 24 hours, first or second-generation Cephalosporin.
- Type 3a-c: 5 days amoxicillin or clavulanic acid or ampicillin-sulbactam or 5 days third generation cephalosporin.
- In the case of faecal contamination (farmyard injury or open pelvic fracture) use will be made of piperacillin; tazobactam; a carbapenem or third generation cephalosporin plus metronidazole.

The current BOAST4 guidelines are as follows[16, 17]

1. Co-amoxiclav 1.2g 8-hourly or a cephalosporin such as cefuroxime 1.5g 8-hourly IV as soon after the injury as possible and continued until debridement.
2. Co-amoxiclav or cephalosporin and gentamicin 1.5mg/kg at the time of debridement and co-amoxiclav or cephalosporin continued until definitive soft tissue closure, or for a maximum of 72hrs whichever is sooner.
3. Gentamicin 1.4mg/kg and either vancomycin 1g or teicoplanin 800mg on induction of anaesthesia at the time of skeletal stabilisation and definitive soft tissue closure. These should not be continued postoperatively. The vancomycin infusion should be started at least 90 minutes prior to surgery.
4. For patients with a penicillin allergy, clindamycin can be given instead of Co-amoxyclav or cephalosporin.

Local antibiotics

In the prevention of osteomyelitis in open fractures, the use of local antibiotic-impregnated polymethyl methacrylate (PMMA) bone cement bead-pouch is well known. This is despite the lack of good evidence in literature on its use and efficacy.[18] Several factors surrounding the use of local antibiotics complicate prospective studies.

The objective of using local antibiotics is to maximize concentration in the injury zone and reduce the risk of systemic toxicity.[18] Various studies have indicated this as the ideal antibiotic due to its thermo-stability, wide range of efficacy, low anaphylaxis rates, its ability to be incorporated in the delivery vehicle and the excellent elution properties from PMMA, vancomycin and aminoglycosides.[18] In two studies on all open fractures, Henry *et al.* were the first to show decreased incidences of deep infection in this scenario. Cumulative infection rate fell from 12% to 3.7%.[19,20] With respect to open tibia fractures, Keating *et al.* reported a reduced infection rate (4% versus 16%) when applying antibiotic beads to standardized debridement, intramedullary nail, and delayed wound closure care.[21] While other delivery methods are being produced, PMMA is by far the most widely used. Gels, calcium sulphate pellets and antibiotic-coated implants are other modalities under investigation.

Wound debridement of tibial fractures

Wound debridement is intended to remove any necrotic and infected tissue from the wound and is widely accepted as an important principle in minimizing the incidence of an open fracture infection.[9,4,14] While debriding any open fracture, the standard operating procedure

includes removing debris and foreign bodies, and recognizing and debriding non-viable skin, muscle and bone. To allow the surgeon to do that adequately, wound extension is required to expose the entire injury site. For those cases, where the wound needs extensive debridement, reconstructive soft tissue techniques to be used to achieve wound closure.[22] Crowley *et al.*[7] suggested, that during wound debridement:

1. Normal saline should be regularly used.
2. Restrict antibiotic or antiseptic fluid additives due to inconclusive evidence and potential risk.
3. Methods of low-pressure irrigation to be regularly used.
4. Pulsed lavage devices with a pressure maximum of 15 psi should be used.

Some studies also focused on the timing of the debridement. It was originally suggested not to prolong the surgical debridement for more than 6 hours. It is assumed that this "6-hour statute" comes from a pre-antibiotic rodent study.[23] In 1987, Patzakis *et al.*[10] found that antibiotic prophylaxis time to surgical debridement was more significant than time to debridement. This has been corroborated by many studies, with the latest reporting that, due to the risk associated with after-hour surgery, the debridement of open fractures can be safely deferred to an urgent-elective theatre list without increasing the risk of infection.[17,25,26] It was also found to be better when the primary debridement was done by an experienced surgical team.[17,25,26] This was confirmed by comparing the outcome of open tibia fractures in a dedicated orthopaedic operating room (DOTOR) during daylight hours with those in an emergency operating room (OCOR). Although similar infection rates were found, less unplanned surgery and uncomplicated fracture union occurred in the DOTOR group.[27]

The BOAST4 guidelines[16] state that:

- Surgery to achieve debridement, fixation and cover of open fractures of the long bones, hindfoot or midfoot should be performed concurrently by consultants in orthopaedic and plastic surgery (a combined orthoplastic approach).
- Perform debridement immediately for highly contaminated open fractures within 12 hours of injury for high-energy open fractures (likely Gustilo–Anderson classification type 3a or 3b) that are not highly contaminated within 24 hours of injury for all other open fractures.

Fracture stabilisation of open tibial wounds

As recommended by Wani et al, principles of fracture stabilization of open tibial wounds include:[15]

1. Ability to maintain or correct displacement, including alignment and rotation.
2. Minimal additional damage to soft tissue or bone.
3. Preserving blood supply.
4. Providing an appropriate mechanical setting for bone healing.
5. Low associated infection incidence.
6. Facilitates healing of soft tissue.

Also relevant is the timing of this procedure. Further soft tissue damage and bacterial spread are reduced by restoring stability and preventing fracture movement. In fact, there is an increase in blood flow to the limb and a decrease in discomfort and oedema. The fixation options are also controversial, including external fixators as well as internal fixation options. The merit of the different fixation options falls outside the scope of this project and will not be discussed in more detail.

Soft tissue management of tibial fractures

Due to its subcutaneous existence, the tibia has been shown to be more vulnerable to post-open fracture infection.[10] As with initial debridement and skeletal stabilization, soft tissue envelope control is of paramount importance in terms of infection and union rates. It is accepted that grade 1 and 2 injuries can be safely closed after the initial debridement if there is no question about residual muscle necrosis or pollution.[4,28] The time delay to definitive closure remains at the heart of the debate, from the initial injury to the definitive soft tissue reconstruction of grade 3 injuries in particular. Within the literature, this has been thoroughly studied, with many recent studies contributing to the body of evidence. Many authors indicate that to avoid complications, 'early' wound coverage is of utmost importance. The exact time frame of 'early versus delayed' has not yet been fully defined, but Godina's suggestion of less than 72 hours is widely accepted as ‘early’ cover.[29] Several authors have tried to clarify the finer nuances surrounding this topic since the mid-1970s. Many of these authors' results and recommendations have been updated due to advances in soft tissue management, especially in the field of microsurgery. Since sub-classifying grade 3 injuries in 1976, Gustillo and Anderson[4] considered these injuries to be the most difficult to

successfully manage. The rate of infection in grade 3 injuries was 44% in the original retrospective examination. After a care plan was introduced, the rate decreased to 9%. These injuries were managed through an open technique. Following irrigation and debridement, skin grafts were applied from day five or six, while a good base of covering granulation tissue develops. In grade 3 injuries, Cierny *et al.*[30] compared infection and malunion rates in cases closed within 7 days versus cases closed thereafter. They found that patients with early wound cover had lower rates of infection (4% vs. 50%) and malunion (4% vs. 17%). Similar findings have been made by Caudel[31] and Fischer *et al.*[32] However, Yaremchuk *et al.*[33] and Godina[29] recognized in the 1980s the significance of effective orthopaedic and plastic coordination in the successful treatment of these injuries; though, they differed on the timing of wound care. In more modern literature, the Webb *et al.* LEAP study group[34] found that there was no difference in the rate of infection in patients with closure of the wound before or after 3 days. Further research by Pollak *et al.* LEAP subgroup[35] grouped time to wound coverage and compared rates of infection. They found no difference in groups of less than three days, four to seven days or more than seven days. Nevertheless, a complication rate of 32% has been reported in the group of more than 7 days to wound closure. D'Alleyrand *et al.*[36] recorded a 11% increase in wound complications and a 16% increase in infection rate every day after seven days of delay in coverage. Since Godina's work was published in 1986, the concept of earlier more aggressive wound closure has been promoted. This concept was further expanded with the' fix and flap ' protocol popularized by Gopal *et al.*[26,37] and Naique.[24] This protocol includes immediate (at the time of primary debridement) soft tissue cover and intramedullary nailing in a single surgical setting. The rationale behind this concept is the early introduction of cellular and humeral elements, essential for the healing process. By achieving soft tissue cover within 72 hours, the complication rates decreased from 19% to 3%.[37] Matthews *et al.*[38] concluded that achieving conclusive soft tissue and skeletal stabilization in a single seat on grade 3 open tibial fractures is more critical than achieving this within 72 hours of injury. In patients with conclusive soft tissue control and skeletal stabilization in the same environment, the incidence of deep infections was 4.2%. While in patients who had done this in separate sessions, the rate of infection was 34.6%. By comparing the rates of deep infections in patients with conclusive skeletal stabilization and treatment of soft tissue before or after 72 hours, the rates were 20% and 12.2% respectively.

Current BOAST4 guidelines[16] state: 'Closure or preservation of definitive soft tissue should be reached within 72 hours of injury if it cannot be done at the time of debridement[16].

Negative pressure wound therapy

No discussion on soft tissue treatment of open fractures is complete before addressing negative pressure wound therapy (NPWT). NPWT has been a breakthrough in the treatment of serious open fractures since it was approved by the Food and Drug Administration (FDA) in 1997. This is particularly true if it is not possible to achieve soft tissue coverage in the primary environment. The untreated wounds become quickly colonized to the hospital environment. Extensive animal and other studies reported on the use of NPWT on open fractures. Such studies have proposed that NPWT decreases oedema, reduces bacterial loads, improves the production of granulation tissue and facilitates wound healing.[39,40] In the possible contaminating hospital environment, it has also been shown to effectively seal the wound.[41] NPWT addresses three major concerns in serious open fractures, namely haematomas, soft-tissue healing and exposed bone coverage. Argenta *et al.*[42] found that NPWT applied after open fracture surgical debridement produces a desirable tissue survival condition by removing oedema and increasing perfusion. Due to the humid environment produced, bone desiccation is minimized. Schlatter *et al.*[43] concluded in a systematic review that NPWT, used to in the setting of grade 3b open tibia fractures, leads to lower infection rates compared to gauze dressings. They also found evidence to support the use of NPWT beyond 72 hours, without increased complication rates and a reduction in the rates of flaps being utilized. Most studies support the use of NPWT as a temporary dressing before conclusive soft tissue closure can be achieved.[41,44,45] Used as a temporary dressing, Dedmond *et al.*[41] demonstrated a reduced requirement (at 58%) for major soft tissue coverage in high-energy open tibial fractures, although infection rates and non-union rates were close to literature controls. Bhattacharyya *et al.*[45] cautioned in his study against NPWT delaying the definitive closure of soft tissue beyond 7 days without causing higher infection rates. Rinker *et al.* [56] reversed this finding by showing that the use of NPWT decreased the infection rate from 18% to 6% in patients with soft tissue closure beyond 7 days. Steiert *et al.*[46] reported similar findings when temporary NPWT was applied in patients with soft tissue closure before 72 hours and those after 72 hours.

BOAST4 recommendations for skeletal fixation soft tissue management are intricately intertwined and BOAST4[16] summarizes the following:

1. Perform fixation and definitive soft tissue cover: Simultaneously with debridement if the next orthoplastic list requires this to occur within the time of debridement, or

within 72 hours of injury if definitive soft tissue cover at the time of debridement is not feasible.

2. When using internal fixation, achieve at the same time a conclusive soft tissue cover.
3. When immediate soft tissue cover has not been done, consider negative pressure wound treatment after debridement.

Conclusion

Although there is extensive literature on the management of soft tissue in open tibia fractures, there are still many ongoing controversies. First world guidelines such as BOAST4, used to direct the care of these injuries, are by their own admission, based mostly on poor evidence.[16] In our tertiary hospital in South Africa, the standard of treatment in these guidelines, particularly with regard to the timing of treatment, is largely unattainable.

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Chapter 2

Publication ready Manuscript

Soft tissue reconstruction of Gustilo-Anderson grade 3b open tibia fractures at a tertiary hospital: A retrospective case series

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Abstract

Introduction: Management of Gustilo-Anderson grade 3b tibia fractures are challenging due to the high rate of complications which includes infection, nonunion and possible amputation. Due to limited soft tissue coverage of the tibia antero-medially, open fractures remain a treatment challenge. Despite many advances, the ideal time delay to definitive soft tissue cover remains controversial.

Aim: We aimed to investigate the management strategy and the outcome of soft tissue reconstruction of Gustilo-Anderson grade 3b tibia fractures at a tertiary hospital in Cape Town, South Africa.

Methods: A retrospective study was conducted on 22 patients who underwent soft tissue reconstruction for grade 3b tibia fractures from January 2014 to July 2017. Patient demographics, comorbidities, injury characteristics and management practices such as time to debridement, relook time, Negative Pressure Wound Therapy (NPWT), soft tissue coverage and complications were recorded.

Results: Most patients were males (n=18; 81.8%) with an average age of 39.3 years. Pedestrian vehicle accidents accounted for 45.4%(n=10), motor-vehicle accidents (n=6; 27.3%) and gunshot wounds (n=2; 9.1%). The commonest site of injury was the middle third of the tibia (n=13; 59.1%), distal third (n=7; 31.8%) and proximal third (n=2; 9.1%). Most patients (n=18; 81.8%) were debrided within 24 hours. The mean times for NPWT prior to cover was 12.5 days and for soft tissue cover 13.7 days (range 2-35), respectively. Fasciocutaneous flaps (n=11; 50%) were predominantly used as cover, then pedicled muscle flaps (n=8; 36.4%), free flaps (n=2) and skin graft(n=1). Most patients (n=13; 59.1%) received satisfactory outcomes. Seven (31.8%) required soft tissue revisions. Three patients (13.6%) suffered complications namely, complete flap loss resulting in amputation, partial skin graft loss and soft tissue infection, respectively. Patients who underwent debridement after 24 hours reported the least complications and there appeared to be better outcomes in the relooks beyond 48 hours.

Conclusion: Despite achieving outcomes which concur with other published studies, the BOAST 4 guidelines were not fully reflected in our management strategy. We will require larger numbers in future studies to formulate a standardized management protocol going forward.

Keywords: Gustilo-Anderson grade 3b tibia fracture, fasciocutaneous flap, muscle flap, complications

Introduction

Open tibial fractures are commonly representative of high-energy trauma that results in significant damage to adjacent soft tissues and neurovascular structures.[1] Crush injuries predominates as the most common cause of these open fractures, followed by falls from a standing height and road traffic accidents; and it is more prevalent in males than females.[2] The annual incidence of open long bone fractures has been estimated at 3.4 per 100 000 population.[3]

Due to the limited soft tissue coverage of the tibial bone anteromedially in the subcutaneous layer, open tibial diaphyseal fractures remain a major treatment challenge. Surgical irrigation and debridement is a critical step in controlling infection and promoting healing. Historically, open fractures were treated within 6 hours of injury as it demonstrated benefits to wound recovery.[4-5] However, recent studies show no statistical significance in infection rates for irrigation and debridement delay up to 12 hours, given that antibiotic treatment was provided.[6-7]

The ideal time delay to definitive soft tissue cover, moreover, remains controversial. Many experts promote 'early' wound coverage to reduce infection and complications risk, even though, there is no consensus on the definition of early versus delayed reconstruction. Godina identified a period of less than 72 hours as early coverage.[8] This was further expanded as the 'fix and flap' protocol involving soft tissue cover and internal fixation in a single surgical setting.[8-11]

Early soft-tissue restoration has, however, been indicated to dramatically improved the outcome of these fractures.[8] Free flap (76.9%) and the dorsalis pedis island flap (64.7%) scored the highest success rate, compared to the muscle flap (at 53.1%) and cross-leg flap (15.8%).[12] The muscle flap and dorsalis pedis island flap is however favoured due to its low complication rate, shorter hospital stay and shorter theater time.[12-13] In 2000, a study further reported that nine pedicle flaps and 75 free muscle flaps only recorded a 3.5% failure rate

due to the immediate internal fixation of soft tissue the wound received within the 72 hour period, and the combined orthopaedic and plastic surgical approach which was followed.[9]

Despite advances in soft-tissue management techniques and an increasing number of implant options, it is extremely difficult to achieve satisfactory treatment outcomes in open fractures of the tibia.[14] Contamination at the fracture site and destruction of the surrounding soft-tissue envelope increase the risk of complications.[15-16] Open tibial diaphyseal fractures remain a major treatment challenge that is associated with substantial rates of infection (11% to 38%), nonunion (7% to 60%), and calls for secondary operative procedures (100%) to achieve fracture union and soft-tissue coverage in patients whose limbs are salvaged.[1,14,17-19]

Numerous classification systems have been developed to characterize open fractures, but the Gustilo and Anderson classification remains the most widely used system to classify the degree of severity of exposed fractures.[4] Management of these fractures involve a step-based approach, as described in Advanced Trauma Life Support (ATLS), that includes initial emergency management, primary and definitive orthopaedic management, soft tissue reconstruction and rehabilitation.[20] The treatment principles of open fractures include antibiotic coverage, wound assessment, critical neurovascular injury assessment, early washout and debridement of devitalized tissue, external or internal fixation and soft tissue reconstruction.[21] Even though, the British Orthopaedic Association (BOA) and British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) introduced a recent stepwise guide for the management of traumatic lower extremity injury; there remains a lack of universal protocol for management of extensive lower extremity injury due to the variable clinical outcomes of numerous studies using different methods, uniqueness of each injury and the influence of independent patient factor.[22-26]

Grade III open fractures of the tibia represent a serious injury and is almost invariably a high-energy fracture characterized by extensive soft-tissue damage or loss, bone exposure with periosteal stripping, and contamination.[4] Severe open tibial fractures requiring soft tissue

cover are challenging injuries that require early specialized intervention for optimal outcomes.[27] With the wide acceptance of a combined orthopedic and plastic surgical approach to manage the Gustilo-Anderson grade 3b standards of care, there has been multifactorial improvement in patient outcomes. The value of complex reconstructive surgery after severe open limb trauma can only be judged by satisfactory functional outcomes.

The present study aimed to investigate the management strategy and outcomes of soft tissue reconstruction of Gustilo-Anderson grade 3b tibia fractures at a tertiary hospital in Cape Town, South Africa.

Methods

Study Design: A retrospective study was conducted on patients who underwent soft tissue reconstruction for Gustilo-Anderson grade 3b tibia fractures from January 2014 to July 2017 at Groote Schuur Hospital in Cape Town, South Africa. The inclusion criteria for the study were as follow: patients diagnosed with Gustilo-Anderson grade 3b tibia fractures; age above 14 years and the availability of a minimum of 12 months follow up.

Data Collection and analysis: Basic demographic information such as age, gender and co-morbid conditions were collected. Factors related to injury such as mechanism of injury, site of fracture, and type of soft tissue injury were also recorded. Data with respect to wound management such as time to debridement, relook time and frequency, NPWT (Negative Pressure Wound Therapy), type and time of soft tissue coverage, soft tissue healing and complications were also recorded. Data was analyzed using descriptive statistics on the continuous data, with calculation of means (with minimum and maximum values); frequency and percentages for the dichotomous data. STATA statistical package version 14 was used to analyze the data.

Results

Patient demographics and injury characteristics: A cohort of sixty patients was analyzed, but only twenty-two patients met the inclusion criteria. The majority were males (n=18; 81.8%), with a mean age of 33.9 years (15-69); 72.7% (n=16) of patients were in the 20-39 year age range (*Table I* below). More than 50% of patients had no medical comorbidity. Seven patients (32%) were smokers.

Pedestrian vehicle accidents (PVA) (n=10; 45.4%) accounted for the largest cause of open tibia fractures, followed by motor-vehicle accidents (MVA) (n=6; 27.3%) and gunshot wounds (GSW) (n=2; 9.1%). The commonest site of injury occurred at the middle third of the tibia (n=13; 59.1%), followed by the distal third (n=7; 31.8%) and proximal third (n=2; 9.1%).

Table I: Demographic and injury characteristics of open tibial fracture patients

Variables		**n (%)**
	n	22
Gender	Males	18 (81.8)
	Females	4 (18.2)
Age (years)	15-19	1 (4.55)
	20-29	7 (31.8)
	30-39	9(40.91)
	40-49	2 (9.09)

	50-59	2 (9.09)
	60-69	1 (4.55)
Co-morbidity	Smoking	7 (31.8)
	Hypertension	2 (9.09)
	Human Immunodeficiency virus (HIV)	1 (4.55)
	None	12 (54.55)
Mechanism of injury	Motor vehicle accidents	6 (27.3)
	Pedestrian vehicle accidents	10 (45.4)
	Gunshot injuries	2 (9.1)
	Others	4 (18.2)
Site of Injury	Proximal	2 (9.1)
	Middle	13 (59.1)
	Distal	7 (31.8)

Primary and surgical management of open tibial fractures: Most of the patients were debrided within 24 hours (n=18; 81.8%) of injury, (*Table II* below). Nearly half of the patients received the relook procedure after 48 hours (n=10; 45.45%), and the relook frequency was one or more times in 68% (n=15) of patients.

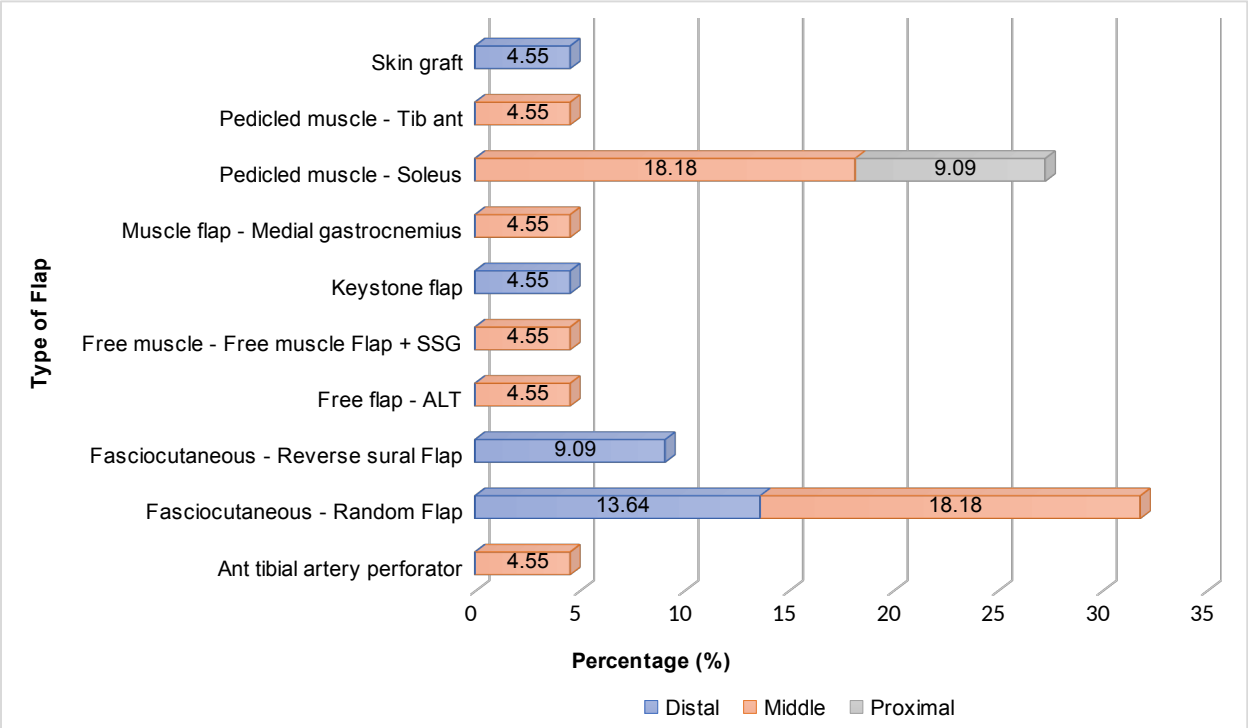
NPWT dressing occurred at an average of 12.5 days post-injury (range 2-42). Seven patients (31.8%) received NPWT dressings within one-week post-injury; five patients (22.73%) within 2 weeks and four patients (18.2%) within three-weeks before definitive tissue cover. Only two patients are shown to have received their NPWT dressing four or more weeks post-injury.

Soft tissue cover occurred at an average of 13.7 days post-injury (range 2 - 35). A number of soft tissue flaps were used, of which random pattern fasciocutaneous flaps (n=7; 31.8%) and pedicled muscle flaps (n=6; 27.3%) predominated.

Table II: Primary management practices in Gustilo Anderson grade 3b open tibial fracture patients

Variables		n (%)
Time of first debridement	6 – 12 hours	4 (18.2)
	12 – 24 hours	9 (40.9)
	>24 hours	9 (40.9)
Relook time	≤48 hours	5 (22.73)
	>48 hours	10 (45.45)
Relook procedure frequency	1	8 (36.4)
	2	7 (31.8)
	3	2 (9.1)
	4	1 (4.6)
	5	1 (4.6)
	>5	1 (4.6)
Duration of NPWT dressing	1 week	7 (31.8)
	2 weeks	5 (22.73)
	3 weeks	4 (18.2)
	4 weeks	1 (4.6)
	>4 weeks	1 (4.6)
Bone cover type and name	Fasciocutaneous – Random pattern flap	7 (31.8)
	Fasciocutaneous – Reverse sural flap	2 (9.1)
	Keystone flap	1 (4.6)
	Free flap - ALT	1 (4.6)
	Free Rectus Abdominis muscle + SSG	1 (4.6)
	Pedicled muscle - Soleus	6 (27.3)
	Pedicled muscle – Tib ant	1 (4.6)
	Pedicled Muscle – Medial gastrocnemius	1 (4.6)
	Ant tibial artery perforator	1 (4.6)

Figure 1. Type of Flap Cover by Site of Injury



Random pattern fasciocutaneous flaps used in seven patients (31.8%) were applied to the distal (n=3, 13.6%) and middle third of the tibia (n=4, 18.2%) (*Figure 1* above). Pedicled muscle flaps were used in the middle third in 4 patients (18.2%) and proximal third (n=2, 9.1%). The reversal sural flap was utilized distally in two patients (9.1%).

Outcomes of soft tissue reconstruction: Most of the patients received satisfactory outcomes following soft tissue reconstruction (Table III below). Of the 17 patients (76.5%) who reported bone coverage within 3 weeks post-injury; seven patients (31.9%) were discharged with no further intervention. Seven patients (31.8%) required soft tissue revisions post initial cover. Nearly two-thirds of patients (n=13; 59.1%) did not report any complications, whereas the remainder were found to have at least one of the five reported

complications. Only one patient (4.6%) underwent an amputation following osteomyelitis and complete flap failure.

Table III: Outcomes of Soft tissue reconstruction

Variables		n (%)
Bone cover time post-injury	Ist week	7 (31.8)
	2nd week	6 (27.3)
	3rd week	4 (18.2)
	4th week	2 (9.1)
	>5th week	2 (9.1)
	2 weeks	4 (18.2)
	3 weeks	2 (9.1)
	4 weeks	6 (27.3)
	5 weeks	1 (4.6)
	6 weeks	1 (4.6)
	>6 weeks	2 (9.1)
Soft tissue cover revisions	No	15 (68.2)
	Yes	7 (31.8)
Type and frequency of complications	Amputation	1 (4.5)
	Complete flap loss	3 (13.6)
	Partial SSG loss	2 (9.1)
	Soft tissue infection	1 (4.5)
	Soft tissue infection & SSG loss	1 (4.6)
	No complications	13 (59.1)

Three patients (13.6%) reported complications, such as complete flap loss resulting in amputation, partial skin graft loss and soft tissue infection.

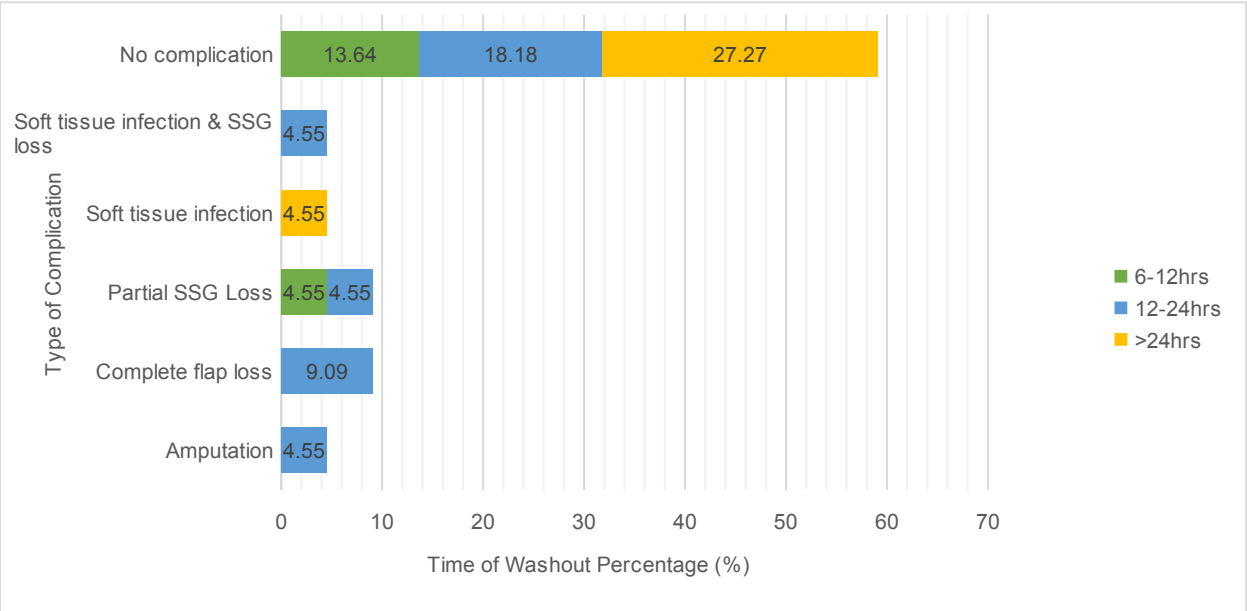
Figure 2. Complication according to flap type

Complications occurred with random pattern fasciocutaneous flaps (n=3; 13.6%) and with pedicled muscle flaps (n=2; 9%). In the random pattern flaps, complete flap loss occurred in two patients (9.1%) and partial skin graft loss (n=1; 4.5%) and soft tissue infection with skin graft loss (n=1; 4.5%) occurred in pedicled muscle flaps. The patient who received an amputation (4.5%) initially had an anterolateral thigh (ALT) free flap (*Figure 2*).

Thirteen patients were debrided within the first 24 hours. Five of them (22.6%) experienced various complications. Interestingly, those patients who were debrided beyond 24 hours,

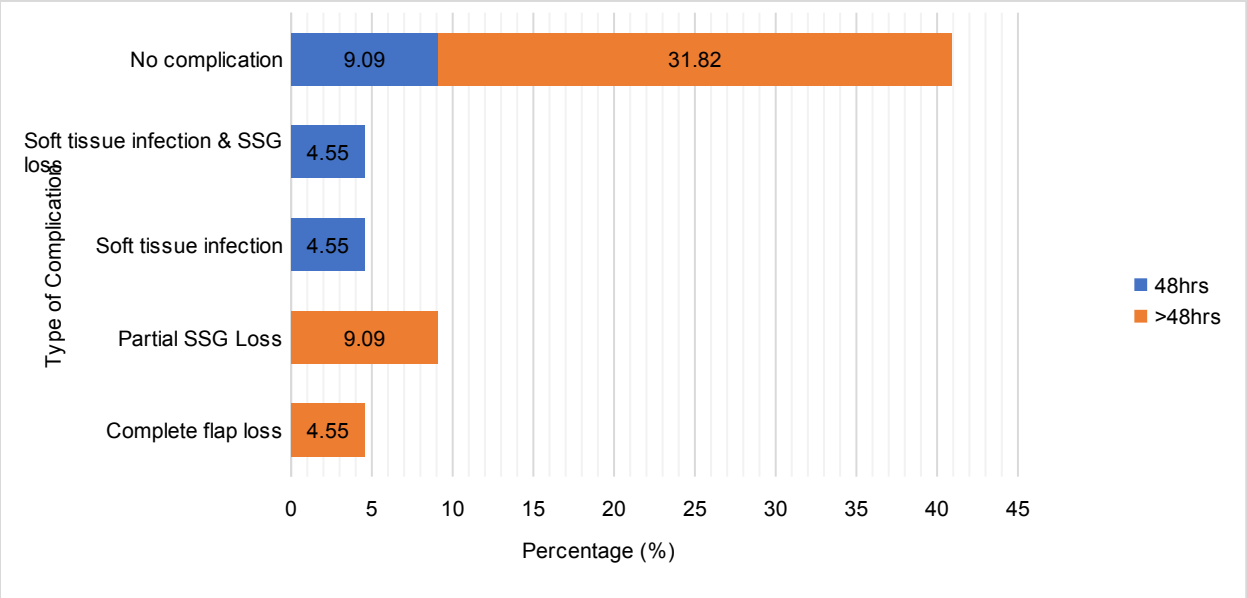
reported the least complications; 27.3% (n=6) had no complications, and only one patient (4.5%) experienced soft tissue infection.

Figure 3. Type of complication by time of washout



There appeared to be better outcomes in the delayed relook time of greater than 48 hours (n=7; 31.8%) with reduced revision requirements, earlier discharge time and less complications (*Figure 4* below).

Figure 4. Relook procedure time by type of complication



Discussion

Our study demonstrates the outcomes of soft tissue reconstruction of Gustilo - Anderson grade 3b tibia fractures at a tertiary hospital in Cape Town, South Africa over a three - year period. We concur with the relevant literature which highlights that 72.7% of males aged 20-39 years are at the highest risk for open tibial fractures.[28-30] Also, road traffic accidents continue to be cited as the leading cause of these high energy fractures.[28,31-32] Similarly, our study findings show that vehicle accidents to predominate in over 70% of cases.

When considering injury characteristics, 59.1% of open fractures occurred at the middle third of the tibia, followed by the distal third in 31.8% of cases and the proximal third in 9.1% of the cases. Studies show that the incidence of middle third tibia fractures were most prominent; one investigation particularly indicated that middle third fractures comprised 76.6% (n=239) of the sample.[33]

It remains clear that these challenging injuries require early specialized intervention for optimal outcomes. For the primary management of tibia fractures, initial debridement was

performed in close to 60% of patients within 24 hours of initial presentation, whereas the remainder received debridement after 24 hours. Even though controversy exists across various guidelines about the “6-hour rule” of providing treatment, which is indicated to reduce infection and complication risk, the present study highlights otherwise.[34-36] Unexpectedly, our study showed that the majority of the patients relooked after 48 hours experienced fewer complications.

More than 50% of patients underwent NPWT dressing within the first two weeks post-injury. Early or delayed wound closure is debatable, with many authors supporting delayed wound closure, whilst others promote early coverage citing its potential advantages and benefits[9,37,39]

Amongst the various types of soft tissue cover flaps used, the random pattern fasciocutaneous flap (31.8%) and pedicled muscle flap (27.3%) predominated. Soft tissue management of the Gustilo Anderson grade 3b fracture is complex. The potential advantages of using fasciocutaneous flaps to treat these fractures include their simplicity, availability, versatility replacing “like with like” and preserving underlying muscle function.[40-41] Other studies report the use of fasciocutaneous flaps in up 85% of cases.[42] Even though the use of fasciocutaneous flaps is popular; a study by Hallock *et al*. reported that 15% of patients received revisions post-bone cover due to peripheral vascular insufficiency.[41] This study reported that up to 43% of patients receiving random pattern fasciocutaneous flaps required revisions.[40] Contrary to this, patients who underwent fasciocutaneous reverse sural flap had the best treatment outcomes with no complications. Our study results support this finding where 13.6% of the random pattern fasciocutaneous flaps underwent complications which include complete flap loss (9.1%) and soft tissue infection (4.5%).

Despite similar trends, our findings are underpowered due to the small sample size. Inconsistencies exist with recent studies that revealed an 87.5% success rate with the use of

fasciocutaneous flaps.[44] Similar to this, several studies demonstrated the use of pedicled soleus muscle flaps in open tibial fractures.[10,44] While few studies demonstrated reduced healing time and higher infection rate, other studies revealed a lower necrosis rate in case of the soleus.[10,45-46]

The major study limitations were its retrospective nature with a poor sample size not large enough for statistical and quantitative subgroup analysis. Nevertheless, this preliminary study revealed the pattern of primary and surgical management practices performed within a tertiary hospital setting, and it assessed the outcomes of commonly used practices which has the potential to be developed as a standardized protocol in this facility after evaluation of a larger sample size.

Conclusion

Based on our outcomes which concur with the literature, it would not be possible to conclude a definitive working plan or summary of the wider practices adopted at the hospital as the sample size was small. Contrary to BOAST 4 guidelines, our key findings include better outcomes when initial debridement occurred beyond 24 hours and when relook surgery appeared after 48 hours. Future studies with a larger sample size are recommended from which a standard working protocol can be developed for this facility.

Conflict of interest

The authors declare they have no conflicts of interest that are directly or indirectly related to the research.

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Data Collection Sheet

<table>
<tr><td>Survey Code</td><td></td></tr>
<tr><td>1. Patient Name:</td><td></td></tr>
<tr><td>2. Age Group:</td><td>
<table>
<tr><td>15-19</td><td>21-24</td><td>25-29</td><td>30-34</td></tr>
<tr><td>35-39</td><td>40-45</td><td>46-49</td><td>50-54</td></tr>
<tr><td>55-59</td><td>60-64</td><td>65-69</td><td>70+</td></tr>
</table>
</td></tr>
<tr><td>3. Date of Injury:</td><td>dd / mm / ccyy</td></tr>
<tr><td>4. Mechanism of Injury:</td><td>
<table>
<tr><td>MVA</td><td>PVA</td><td>GSW</td></tr>
<tr><td colspan="3">Other:</td></tr>
</table>
</td></tr>
<tr><td>5. Site</td><td>
<table>
<tr><td>Right</td><td>Proximal ⅓</td><td>Middle ⅓</td><td>Distal ⅓</td></tr>
<tr><td>Left</td><td>Proximal ⅓</td><td>Middle ⅓</td><td>Distal ⅓</td></tr>
</table>
</td></tr>
<tr><td>6. First Presentation</td><td>
<table>
<tr><td>Groote Schuur hospital</td><td>Secondary level hospital</td></tr>
</table>
</td></tr>
</table>

7. Initial Management (Casualty)	Washout / Antibiotics / Antitetanus
8. Date of Referral to GSH	dd / mm / ccyy
9. Time of Referral to GSH	hr : mins
10. Time of First Washout	< 6hrs / 6-12hrs / 12-24hrs / >24hrs
11. Relook (due to booking on E board)	24 hrs / 48 hrs / > 48 hrs
12. NPWT Dressing	dd / mm / ccyy
13. Relooks	1 / 2 / 3 / 4 / 5
14. Bone Cover: Day post-injury	dd / mm / ccyy
15. Type of Cover	Skin Graft / Muscle Flap / Fasciocutaneous / Free Flap
17. Revisions post-Bone Cover	Yes / No Why: 1. 2. 3.
18. Complications	

	Type	Notes
	Flap loss (Partial/ complete)	
	Soft Tissue Infection	

Instructions for Authors

Scope and Policy

The scope of publication encompasses all orthopaedic surgery sub–disciplines including paediatric orthopaedics, hip, knee, tumour and sepsis, spine, shoulder and elbow, foot and ankle and hand surgery. In addition the journal addresses the subjects of orthopaedic service delivery, teaching, training and research. Publications should influence orthopaedic care on our continent.

The *South African Orthopaedic Journal* aims to advance the knowledge of all aspects of musculoskeletal medicine through publication of:

- Original research articles.
    - Clinical research
    - Basic science and theoretical research
- Review articles.
- Invited expert opinions.
    - A review of significant local or international publications journal article or cluster of articles dealing with a similar topic for the purpose of conveying a useful message.
- Editorials.
- Letters to the editor.
    - Forum to raise issues or debate aspects of previously published papers.

Criteria for publication

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented in an appropriate fashion and are supported by the data.
- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
- Other ‘contributors’ can be acknowledged at the end

of the manuscript together with their contribution.
- Authors of manuscripts representing a multi–centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.
- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.

Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health–related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process–of–care changes.
- Clinical trials should be registered in a public trials registry in accordance with International Committee of Medical Journal Editors recommendations.
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design that was used (listed below):

Randomised trials	CONSORT
Observational studies	STROBE
Systematic reviews	PRISMA
Case reports	CARE
Qualitative research	SRQR
Diagnostic / prognostic studies	STARD
Quality improvement studies	SQUIRE
Economic evaluations	CHEERS
Animal pre–clinical studies	ARRIVE

Study protocols	SPIRIT

- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Role of funding source

- Authors are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement, then this should be stated.

Formatting of Submissions

Text formatting

- Use Helvetica or Arial font, size 11.
- Use double line spacing throughout the document.
- Number the pages of the blinded manuscript consecutively.
- Use italics for emphasis.
- When referring to an article with multiple authors please use the following format: Rabinowitz *et al*. published their retrospective review.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

- Use no more than three levels of displayed headings.

Abbreviations

- Define abbreviations and acronyms at first mention and use consistently thereafter.

Units

- Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: … wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures should be understandable without the main text.
- For radiographs please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Figures should not be imbedded in the text file, but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in the text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, … high–energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table heading explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower–case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.
- Do not embed tables in the text file, but submit them as separate individual files. Each table should be a separate file, entitled Table I, Table II, etc.
- We accept a maximum of eight tables.
- Do not duplicate information given already in the text.
- Do not submit any figures, photos, tables or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written

permission from the copyright holder to use that content.

References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.
- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
- Authors should add DOIs to all references in articles.
- Accuracy of references is the author's responsibility and the author is to verify the references against the original documents.
- Manuscripts in preparation, unpublished data (including articles submitted but not in the press) and personal communications may not be included in the reference listing. They may be listed in the text in parentheses only if absolutely necessary to the contents and meaning of the article.
- The titles of journals should be abbreviated according to the style used in Index Medicus, obtainable through the website http://www.nlm.nih.govshould
- The following format should be used for references:

Journal article:
Sidhu GS, Ghag A, Prokuski V, Vaccaro AR, Radcliff KE. Civilian gunshot injuries of the spinal cord: a systematic review of the current literature. Clin Orthop Relat Res 2013;471:3945-55.

Ideally, the names of all authors should be provided, but the usage of 'et al.' in long author lists (more than six authors) will also be accepted: Fong K, Truong V, Foote CJ, et al. Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. BMC Musculoskelet Disord 2013;14:103.

On–line journal article:
Caetano–Lopes J, Lopes A, Rodrigues A, et al. Upregulation of inflammatory genes and downregulation of sclerostin gene expression are key elements in the early phase of fragility fracture healing. PLoS One 2011;6:e16947.

Web reference (with authors):
Cierny G, DiPasquale D. Adult osteomyelitis protocol. http://www.osteomyelitis.com/pdf/treatment_protocol.pdf. (date last accessed 05 March 2013).

Web reference (no authors listed):
No authors listed. International commission on radiological protection. http://www.icrp.org (date last accessed 20 September 2009).

Chapter in a book:

Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). Spinal Trauma. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

Dissertation:
Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

Abstract:
Peterson L. Osteochondritis of the knee treated with autologous chondrocyte transplantation [abstract]. ISAKOS Congress, 2001.

Structure and content of submission

- We accept a maximum of 3500 words including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta–analysis, at the discretion of the Editor–in–Chief.
- Please follow the following structure when preparing your submission.
    - Title page (Title, authors and affiliations, corresponding author and declarations)
    - Blinded manuscript (Abstract, key words, introduction, methods, results, discussion, funding sources, conflict of interest statement, ethical statement, acknowledgements and references)
    - Tables (with headings), each as a separate file.
    - Figures (with legends), each as a separate file.

Title page

Title

- The title should be concise and informative.

Author names and affiliations

- Please provide the following information for each author:
    - Full names and surname, as well as title
    - Qualifications
    - Affiliation and address
    - ORCID ID (see Article Submission section)
- Please check that all names are accurately spelled.
- Indicate all affiliations with a lower–case superscript letter immediately after the author's name and in front of the appropriate affiliation details.
- Provide the full postal address of each affiliation, including the country name and, if available, the e–mail address of each author.

Corresponding author

- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post–publication.
- Ensure that the e–mail address and permanent address is given and that contact details are kept up to date by the corresponding author.
- Please note that the corresponding author's contact details will be provided in the final article.
- Provide the following information for the corresponding author:
    - Full names and title
    - Affiliation
    - Physical address
    - Postal address
    - Telephone Number
    - E–mail address

Declarations
Authors are to insert a section at the end of the title page entitled declarations. Following the declarations all authors need the to sign the document (please provide name of author, signature and date). The following statements are required under the declarations section:

a. Authorship
   The authors confirm that all authors have made substantial contributions to all of the following:
    - The conception and design of the study, or acquisition of data, or analysis and interpretation of data
    - The drafting the article or its critical revision for important intellectual content
    - Final approval of the version to be submitted.

b. Sound scientific research practice
   The authors further confirm that:
    - The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere
    - No data have been fabricated or manipulated (including images) to support conclusions.
    - This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami–publishing').

c. Plagiarism
   The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.
    - No data, text or theories by others are presented as if

they were the authors' own.
- Proper acknowledgements of others' work has been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks are used for verbatim copying of material.
- Permissions have been secured for material that is copyrighted.

d. Conflict of interest statement
A conflicting interest exists when professional judgement concerning a primary interest (such as the patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It represents a situation in which financial or other personal considerations from authors, reviewers or editors have the potential to compromise or bias professional judgment and objectivity. It may arise for the authors when they have a financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. All potential conflicts of interest need to be declared. The conflict of interest statement should list each author separately by name, i.e.,

'John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A. Mike Schultz has received a speaker honorarium from Drug Company B and owns stock in Drug Company C.'

If multiple authors declare no conflict, this can be done in one sentence.

e. Funding sources
All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated.

f. Compliance with ethical guidelines
- For all publications:

'The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research

Integrity in Singapore, 2010.'

Available from: http://publicationethics.org/resources/international-standards-for-editors-and-authors

Institutional Review Board (IRB) ethical approval must have been given if the study involves human subjects or animals. Please provide the approval number. IRB documentation should be available upon request.

'Prior to commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number'*

- For studies with human subjects include the following: 'All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.'

  'Informed written consent was or was not obtained from all patients for being included in the study.'
- For studies with animals include the following sentence: 'All institutional and national guidelines for the care and use of laboratory animals were followed.'
- For articles that do not contain studies with human or animal subjects: 'This article does not contain any studies with human or animal subjects.'
- If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article.

  The Helsinki Declaration 2008 can be found at http://www.wma.net/en/30publications/10policies/b3/

Blinded manuscript

Abstract

- A structured abstract (maximum of 350 words), summarising the most important points in the article is required.
- The abstract consists of four paragraphs with the subheadings:
  - Aims (it is unnecessary to include an introductory section)
  - Patients and methods

    - Results
    - Conclusion
- References should be avoided. Avoid uncommon abbreviations. If essential they must be defined at their first mention in the abstract itself

Key words

- Immediately after the abstract, provide a maximum of six key words, using standard searchable terms. These key words will be used for indexing purposes.

Level of evidence

- Level 1 to 5.
- Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence–Based Medicine (OCEBM); version 2.1.
- Available from: OCEBM Levels of Evidence Working Group. 'The Oxford Levels of Evidence 2'.Oxford Centre for Evidence–Based Medicine. http://www.cebm.net/index.aspx?o=5653

Introduction

- The introduction should contextualise the study by providing the background to the research; explain the problem that is to be addressed and provide the rationale for the study.
- Briefly outline the relevance of the study with respect to the current literature. Avoid a detailed literature survey or a summary of the results.
- The last sentence should outline the research question or hypothesis.

Patients (or Materials) and methods

- State the methods, outcome measures, and selection criteria. The following aspects need to be described:
    - The study design and research methodology
    - Whether randomisation (with methods) was applied
    - If case controlled, how the controls were selected
    - The time period under review
    - Number of patients/subjects under investigation and why this number was chosen
    - Inclusion and exclusion criteria
    - Case and outcome definitions
    - A description of the procedure or intervention, including post–operative protocol
    - The outcome measures or scores used
    - The minimum follow–up period
    - Statistical analysis paragraph. This should be included at the end of this section to detail statistical tests and package used, the reasons why these tests were used, and what p–value was considered statistically significant. A power analysis is recommended for studies comparing two or more groups.

- Provide sufficient detail so that another researcher can replicate the study.
- The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g., state of disease, choice of treatment).
- Do not describe standard procedure for common operations. Only include new procedures or adaptations to standard procedure.
- If you name any specific product, then it requires the name, city and state/country of the manufacturer.
- Present information in the narrative format and use the past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should be presented in this section.

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow–up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.
- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).
- Avoid using percentages in studies involving well under 100 subjects.
- All results must be backed up with p–values or survivorship analysis. All Kaplan–Meier data should be presented with the confidence intervals. Always present exact absolute p–values, whether significant or not, unless $p < 0.001$.
- However, p–values do not always convey the entire picture and where relevant the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

- The question or hypothesis stated at the end of the introduction should be discussed and either supported or rejected.
- The results must be interpreted clearly and any deficiencies expressed. All possible confounding factors, sources of bias, or weaknesses in the study should be identified.
- Explore the significance of the results of the work, rather than

repeating the results.
- The discussion must point out the relevance of the work described in the paper and its contribution to current knowledge.
- Explain what can be deduced from the results and how will it affect clinical practice.
- Include a review of the relevant literature, placing the results of the study in the context of previous work in this area.
- Discussion of relevant prior research and references must be concise. Avoid extensive citations and discussion of published literature but put emphasis on previous findings that agree (or disagree) with those of the present study.
- Do not repeat the introduction.
- Present the limitations of the study and suggest how the study could have been improved for a future study.
- Avoid making inferences from non–significant trends unless you believe your study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

- Provide a summary statement which conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

Conflict of interest

- 'Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z.'
- If no conflicts of interest exist, state this as follows: 'The authors declare they have no conflicts of interest that are directly or indirectly related to the research.'

Ethical statement

- For studies involving human subjects please include an ethical statement as follows: 'All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.'
- For animal studies please include the following ethical statement: 'All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.'
- If the study did not involve human or animal subjects state that: 'This article does not contain any studies with human participants or animals performed by any of the authors.'
- Please also include an informed consent statement: 'Informed consent was obtained from all individual participants included in the study.'
- Or alternatively, for retrospective studies, please add the

following sentence: 'For this study formal consent was not required.'

- If identifying information about participants is available in the article, the following statement should be included: 'Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.'

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

22 August 2018
HREC REF: 511/2018

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

Dr Marltz Laubscher
Orthopaedic Surgery
H49, OMB

Dear Dr Laubscher

PROJECT TITLE: SOFT TISSUE RECONSTRUCTION OF [illegible] AND [illegible] GRADE 111B OPEN EXTRA-ARTICULAR TIBIAL FRACTURES AT A TERTIARY HOSPITAL IN CAPE TOWN, SOUTH AFRICA: A RETROSPECTIVE [illegible] (HREC REF: 511/2018)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 August 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all future correspondence.

Please note that the ongoing responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval should research at [illegible] occur.

The HREC acknowledges that the student, Dr Elyas Barouni will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M[illegible]N

CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001687
Institutional Review Board (IRB) number: IRB0000019538

HREC 511/2018

Funding sources

- List all funding sources as follows: 'This work was supported by the xxxx (grant numbers xxxx, yyyy).'
- When funding is from a block grant or other resources available to a university, college or department, it is sufficient to name the institute or organisation that provided the funding.
- If no funding was received, state as follows: 'No funding was received for this study.'

Acknowledgements

- Acknowledgements should be placed at the end of the discussion and before the references.
- In this section persons who were involved but did not earn authorship can be acknowledged.
- Statements should be brief. A person can be thanked for assistance or for comments.
- Should not include contributions by editors or referees.

References

- Please refer to the section on Formatting of submissions.

Tables and figures

- Table and figures should not be imbedded in the text file, but should be submitted as separate individual files. Each table should be a separate file, entitled Table I, Figure 2, etc.
- Each table and figure should be provided with a heading or legend.
- Please refer to the 'Formatting of submission' section for further guidelines.

Supporting Document: Departmental Research Ethics Approval Committee

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

HUMAN RESEARCH ETHICS COMMITTEE
29 OCT 2019
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS017: ~~Annual Progress Report~~ / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
✓ Approved	Annual progress report	Approved until/next renewal date	30.10.2020
Not approved	See attached comments		
Signature Chairperson of the HREC	signature removed	Date Signed	1/11/2019

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	29/10/2019		
HREC REF Number	511/2018	Current Ethics Approval was granted until	30/08/2019
Protocol title	Soft tissue reconstruction of gustilo Anderson grade IIIb open extra articular tibial fractures at a tertiary hospital in Cape Town: A retrospective study		
Principal Investigator	Maritz Laubscher		
Department / Office Internal Mail Address	Orthopedic department		
1.1 Does this protocol receive US Federal funding?		Yes	No

2. Protocol status (tick ✓)

	Research-related activities are ongoing
	Data collection is complete, data analysis only
Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.	

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		22
Total number of records or specimens collected, reviewed or stored since last progress report		
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	Yes	No

4. Signature

Signature of PI	signature removed	Date	29/10/2019

(Note: Please complete the Closure form (FHS019) if the study is completed within the approval period)